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EXAMINER

SCHWARTZ, JORDAN MARC

ART UNIT PAPER NUMBER

2873

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/910,355

Applicant(s)

MARMO, J. CHRISTOPHER

Examiner

Jordan M. Schwartz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-24 and 41-44 is/are allowed.
- 6) ☒ Claim(s) 1-14, 17, 18, 25-40, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 15, 16 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5, 7, 9-11, 13-14, 17, 25-26, 29-33, 35-36, 39-40, 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Conrad patent number 3,431,046.

Conrad discloses the limitations therein including the following: a contact lens for use on an eye (abstract) comprising a plurality of radially extending microchannels in the posterior face (Figure 3); to promote the effective tear fluid exchange between the exposed surface of the eye and a surface covered by the lens body (column 3, lines 58-70); a curved peripheral portion surrounding the optic portion (Figure 4); the microchannels extending from the peripheral edge of the lens through a substantial portion of the curved peripheral portion (Figures 3 and 4). Conrad further discloses the microchannels sized and adapted to not interfere with the optic zone function in that the channels are disclosed as not extending into the optic zone (Figure 3); and the claimed depth of the channels (Figure 4). It is believed that Conrad would inherently have the claimed width of the microchannels, this being reasonably based upon the very narrow channels disclosed (Figure 3) and the large width claimed (up to 500 microns), and the

similarity in structure between the microchannels of Conrad (Figure 3) and that of the claimed invention. Conrad further discloses an absence of microchannels in the optic zone (Figure 3); the microchannels equidistantly spaced apart (Figure 3); the microchannels terminating in the peripheral portion (Figure 3); and extending to the optical zone (Figure 3). In reference to claim 17, in Figure 3, any two of the microchannels can be considered as the "first set" and any other two microchannels can be considered as the "second set" and inherently some of the lachrymal fluid that flows into the lens through channels of the first set will flow out of the lens through channels of the second set (the fluid does not flow in and out through the same channel necessarily) and therefore the sets can be considered "in fluid communication with each other". It is believed that Conrad would inherently have the microchannels spaced apart within the claimed ranges, the claimed width and depth within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film as claimed, this being reasonably based upon the vary large ranges claimed as well as upon the similarity in structure between the lens of Conrad and that of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-14, 17-18, 25-27, 29-40 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volk patent no. 5,347,326.

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Volk discloses the limitations therein including the following: a contact lens for use on an eye (abstract) comprising a plurality of radially extending microchannels in the posterior face (Figures 6 and 12, column 14, lines 3-29); to promote the effective tear fluid exchange between the exposed surface of the eye and a surface covered by the lens body (column 14, lines 3-29 and claim 12 in which it is stated that the channels both remove air and allow the flow of tear fluid); a curved peripheral portion surrounding the optic portion (Figures 2 and 3); the microchannels extending from the peripheral edge of the lens through a substantial portion of the curved peripheral portion (Figures 6 and 12). Volk further discloses the microchannels sized and adapted to not interfere with the optic zone function in that the channels are disclosed as not extending into the optic zone (Figure 12). It is believed that Volk would inherently have the claimed depth and width of the microchannels, this being reasonably based upon the disclosed depth and radius of the microchannels (column 6, line 47, column 11, line 35) as well as being based upon the large range of depth claimed (less than 90 % of the width), the large width claimed (up to 500 microns), and the similarity in structure between the microchanneled lens of Volk (Figures 6 and 12) and that of the claimed invention. Volk further discloses an absence of microchannels in the optic zone (Figure 12); the microchannels having a decreased taper in terms of width (Figure 12 i.e. there is some width taper near the ends of the channels); the microchannels equidistantly spaced apart (Figure 12). In reference to claim 17, in Figure 12, any two of the microchannels can be considered as the "first set" and any other two microchannels can be considered as the "second set" and inherently some of the lachrymal fluid that flows into the lens

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through channels of the first set will flow out of the lens through channels of the second set (the fluid does not flow in and out through the same channel necessarily) and therefore the sets can be considered "in fluid communication with each other". In reference to claim 18, Volk further discloses the annular microchannel between (Figure 12, "106"). It is believed that Volk would inherently have the microchannels spaced apart within the claimed ranges, the claimed width and depth within the claimed ranges, as well as the microchannels providing substantially continuous, freely flowing tear film as claimed, this being reasonably based upon the vary large ranges claimed as well as upon the similarity in structure between the lens of Volk and that of the claimed invention. Volk discloses as is set forth above but does not specifically disclose the claimed "anterior face configured to accommodate movement of an eyelid over the anterior face". However, Volk states that the anterior surface can be a spherical surface (column 9, line 29) which would inherently accommodate movement of an eyelid over its face. Regardless, Volk teaches that the lens can be used for not only diagnostic purposes but also for therapeutic purposes (column 1, line 11) and further states that the anterior surface can be "of any configuration for the procedure to be performed" (column 9, line 25). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the anterior face configured to accommodate movement of an eyelid over it since Volk teaches that the anterior face can be of any configuration depending upon its therapeutic use and therefore it would be obvious for it to be configured to accommodate an eyelid if a specific therapeutic use required eyelid movement.

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Claims 3, 27-28 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad in view of Haralambopoulos et al.

In reference to these claims, Conrad discloses as is set forth above but does not specifically disclose the decreasing taper as claimed. Haralambopoulos et al teaches that a contact lens that has microchannels (column 1, lines 12-27) can further have the microchannels tapered as claimed to provide a more effective means of tear fluid exchange (Figure 3B, column 7, line 7). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the channels of Conrad tapered as claimed since Haralambopoulos et al teaches that a contact lens that has microchannels can further have the microchannels tapered as claimed to provide a more effective means of tear fluid exchange.

Claims 6, 12 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad.

In reference to these claims, Conrad discloses as is set forth above but does not specifically disclose the number of channels within the claimed range. However, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have Conrad comprising the number of channels within the claimed range (at least 10 i.e. four more channels than what is disclosed) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Prior Art Citation

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Moss patent number 3,246,941 is being cited herein to show another contact lens that would have read on or made obvious the same claims rejected by the Conrad reference above, however, such rejections would have been repetitive.

Allowable Subject Matter

Claims 19-24, 41-44 are allowed.

Claims 15-16 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: with respect to the allowable subject matter, none of the prior art either alone or in combination disclose or teach of the claimed combination of limitations to warrant a rejection under 35 USC 102 or 103. Specifically, with respect to claims 15-16 and 41-42, none of the prior art either alone or in combination disclose or teach of the contact lens comprising an optical portion, a plurality of radially extending microchannels sized and adapted to promote effective tear fluid exchange between an exposed surface of the eye and a surface of the eye covered by the lens body, the microchannels having the claimed depth and width, and specifically further including first microchannels only in the peripheral portion and second microchannels at least partially in the optic zone. Specifically, with respect to claims 19-24 and 43-44, none of the prior art either alone or in combination disclose or teach of the contact lens comprising a first annular portion, a second annular portion, a first set of microchannels in the first annular portion, a second set of microchannels in the second annular portion, the first and second set in optical

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communication with each other, the microchannels having the claimed depth and width, the lens body including an optical zone and the first set of microchannels extending from an edge of the optical zone to the peripheral edge, and specifically further with the second annular portion circumscribing the first annular portion. Specifically, with respect to claim 47, none of the prior art either alone or in combination disclose or teach of the contact lens comprising the claimed radially extending microchannels having the claimed depth and width, the claimed curved peripheral portion with the microchannels extending from the peripheral edge through a substantial portion of the curved peripheral portion, and specifically further with the microchannels extending into the optical zone of the lens body.

Response to Arguments

Applicant's arguments filed May 19, 2003 have been considered but, with respect to the rejected claims by Volk set forth above, they are not persuasive. Specifically, applicant argues that Volk is a diagnostic and therapeutic lens and does not disclose the anterior surface to accommodate movement of an eyelid. However, Volk discloses that the anterior surface need not be planar and can be spherical which would inherently accommodate movement of an eyelid. Furthermore, it would have been obvious for the anterior surface to be so configured for the reasoning set forth in the rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (703) 308-1286. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

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A handwritten signature in black ink, appearing to read 'JMS', with a large loop at the end.

Jordan M. Schwartz
Primary Examiner
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July 30, 2003